

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH,

Plaintiff,

v.

IMPAX LABORATORIES, INC.,

Defendant.

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) Civil Action No.: 06-222 JJF
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) **PUBLIC VERSION**
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**DEFENDANT'S REPLY BRIEF IN SUPPORT OF MOTION TO COMPEL A
RESPONSE TO INTERROGATORY NUMBER 35**

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I. INTRODUCTION

The opposition of Plaintiff Wyeth (“Wyeth”) to this motion to compel is the latest battle in a war Wyeth has been fighting on all fronts to prevent Defendant Impax Laboratories (“Impax”) from discovering information regarding the extended release venlafaxine formulations that third party Alza Corporation developed in connection with a joint-development agreement with Wyeth – formulations that Impax contends invalidate the asserted claims of the patents-in-suit. Wyeth has objected to and refused to produce documents in response to five separate document requests Impax propounded to discover documents related to the Alza formulations. Wyeth refuses to produce a witness for deposition under Rule 30(b)(6) and recently filed with the Court a misguided motion for protective order to prevent that deposition from going forward. Now Wyeth refuses to answer Impax’s Interrogatory No. 35, which simply asks Wyeth to identify the individual witnesses at Wyeth having information regarding the Alza formulations and to state Wyeth’s contentions as to why it was not obligated to notify the Patent and Trademark Office (“PTO”) of the Alza collaboration and prior art formulations.

Wyeth justifies its refusal to answer the interrogatory by reassuring the Court that, in Wyeth’s opinion, the Alza formulations do not invalidate the asserted patent claims. Wyeth cannot avoid its discovery obligations based on what it hopes will be the Court’s ultimate decision on the merits. Whether the formulations about which Wyeth refuses to provide discovery invalidate the patents is a question for the Court to decide based on the very evidence Wyeth refuses to produce. Impax is entitled to discover the details regarding these formulations and, based on this discovery, present its own arguments to the Court as to why they invalidate the patents-in-suit.

Next Wyeth states that because it has produced some documents of its own choosing related to the Alza joint development, it need not answer this interrogatory. The relatively few documents Wyeth has produced regarding Alza simply do not provide the information requested by the interrogatory. These documents do not identify the witnesses at Wyeth who could testify

as to the ingredients of the Alza formulations. Nor do the documents provide the contents of the formulations directly. And these documents fail to reveal Wyeth's reasons for failing to disclose the Alza formulations or the Alza joint development effort to the PTO.

Because Wyeth cannot dispute that information regarding the Alza formulations are relevant to Impax's claim that those formulations invalidate the patents-in-suit, Wyeth argues that the interrogatory relates solely to inequitable conduct, and that Impax is not entitled to take discovery on Wyeth's failure to provide the Alza formulations to the PTO until it has pled that particular theory of inequitable conduct with particularity. In doing so, Wyeth ignores the provision in Rule 26(b)(1) providing that for good cause, a party may take discovery on any matter relevant to the broad subject matter of the action. Impax has shown good cause to take discovery regarding the Alza formulations here because it has raised the subject matter of the unenforceability of the patents-in-suit, has articulated the information it believes Wyeth wrongfully withheld from the patent and trademark office, and has articulated the way in which that information was material to patentability. Accordingly, this case is unlike the cases upon which Wyeth relies, in which the accused infringer sought discovery related to inequitable conduct without articulating any basis for believing that the discovery would lead to admissible evidence. Impax requires discovery regarding the Alza formulations in order to gather the final details required to plead its theory of inequitable conduct with particularity, and Wyeth should not be permitted to avoid facing this defense by withholding relevant discovery.

Wyeth's argument that the interrogatory is "impossible to answer" is specious. Wyeth knows which of its employees worked on the Alza joint development effort, and Rule 26 specifically sanctions interrogatories that seek the identity of witnesses. The remainder of the interrogatory merely asks Wyeth to state its contentions as to why it was justified in withholding the Alza formulations from the PTO in prosecuting the patents-in-suit. These formulations were particularly material to patentability in light of the fact that Alza now contends that Wyeth's alleged commercial embodiment of the patents-in-suit — Effexor XR® — infringes Alza's patent that grew out of that joint development effort.

II. ARGUMENT

A. Wyeth Improperly Attempts to Avoid an Invalidity Challenge Based on the Alza Formulations by Blocking All Discovery on the Alza Formulation.

1. Wyeth refuses to identify individuals for deposition on the Alza formulations and refuses to produce a witness pursuant to Rule 30(b)(6).

Wyeth cannot dispute that because Impax contends that the Alza formulations invalidate the patents-in-suit, Rule 26 entitles Impax to discover the identity of witnesses having knowledge of the Alza formulations. The Rule specifically provides for the discovery of “the identity and location of persons having knowledge of any discoverable matter.” Fed. R. Civ. P. 26(b)(1).

Instead of disputing this point, Wyeth contends that “Interrogatory No. 35 does not request this information.” (D.I. 89 at 11). This contention is contradicted by Wyeth later in its brief when it complains that the interrogatory is unduly burdensome because it “would require Wyeth to identify *every* person at Wyeth who had some knowledge about the Wyeth/Alza collaboration.” (D.I. 89 at 15). Moreover, Wyeth’s characterization of the interrogatory is flatly wrong. The interrogatory first asks Wyeth whether it contends that the inventors of the patents-in-suit “were not aware of ALZA’S development of an EXTENDED RELEASE FORMULATION comprising VENLAFAXINE beyond the disclosure in publication WO 94/27589.” Declaration of Mary B. Matterer in Support of Defendant’s Motion to Compel a Response to Interrogatory No. 35. (“Matterer Decl.”), Ex. 4 at 12. The Interrogatory further asks Wyeth to identify “all PERSONS who have knowledge of such bases [for Wyeth’s contentions as to why it was not obligated to disclose the Alza formulations to the PTO]” and “what knowledge each PERSON has.” *Id.*, Ex. 4 at 12.

Impax requires the identity of persons at Wyeth with knowledge of the Alza formulations so that it may identify witnesses for deposition on this topic. Impax’s request is limited to those persons having knowledge beyond what is disclosed in “publication WO/94/27589” (the Alza PCT application) because the only way for Impax to discover those formulations that are not disclosed in the Alza PCT application is to depose Wyeth witnesses on this topic or discover

documents. Wyeth has refused to produce documents that reveal the formulations. *See* Section A.2, *infra*. Accordingly Impax is attempting to identify witnesses for individual deposition.

Wyeth's refusal to identify individual witnesses is particularly egregious in light of the fact that Wyeth also refuses to produce a witness to testify on the Alza formulations pursuant to Rule 30(b)(6). Wyeth has filed a motion for protective order and refuses to produce a 30(b)(6) witness on *any* topics until that motion is resolved. (D.I. 90 at 2, 24-25 (filed under seal on Feb. 21, 2007)).

Even if that deposition were to go forward, Wyeth refuses to provide any testimony regarding who had knowledge and awareness of the Alza formulations on the grounds that it does not understand what the words "awareness" and "knowledge" mean. (D.I. 90 at 13). Wyeth has unjustifiably narrowed the scope of testimony it will give regarding the contents of the Alza formulations. Wyeth will only provide testimony regarding the Alza formulations and the release profiles of those formulations "[u]p to March 25, 1996," which it claims is the "effective filing date of the patents-in-suit." (D.I. 82 at 6 ¶¶ 4, 8). Because Impax contends that the priority date of the asserted patents is November 5, 1997, when Wyeth added important new disclosures, the contents of the Alza formulations after March 25, 1996 are relevant to Impax's claim of invalidity and are discoverable. And because "[t]he duty of candor extends throughout the patent's entire prosecution history," information regarding the Alza formulations throughout the period of patent prosecution is relevant to Impax's claim of unenforceability and is discoverable. *Fox Industries, Inc. v. Structural Preservation Systems, Inc.* 922 F.2d 801, 803 (Fed. Cir. 1990).

For the same reasons, Wyeth's offer to answer this interrogatory only by stating whether the inventors of the patents-in-suit were aware of the Alza formulations "as of March 25, 1996" is unacceptable. (D.I. 89 at 11). If the inventors can testify as to the contents and characteristics of the Alza formulations, that information is relevant to invalidity and discoverable even if they only obtained that information after March 25, 1996. And because the inventors had a duty to disclose the Alza formulations to the PTO throughout the prosecution of the patents-in-suit,

whether they became aware of the formulations after Wyeth's alleged priority date is relevant to unenforceability and is discoverable.

2. Wyeth refuses to produce documents containing the information Impax seeks by this interrogatory.

Wyeth's contention that it need not answer this interrogatory because "Wyeth has produced to Impax documents relating to the Wyeth/Alza collaboration" is unsupportable on many levels (D.I. 89 at 11-12).

First, Wyeth has objected to and has refused to produce *any* documents in response to five Impax document requests regarding the Alza formulations under the same improper objection that this information is irrelevant. Reply Declaration of Mary S. Matterer, Ex. 1 at 30-34 (Responses to Requests for Production Nos. 106, 107, 108, 109, 110).

REDACTED

Third, if Wyeth means to answer this interrogatory by invoking Federal Rule of Civil Procedure 33(d), the option to produce business records in lieu of answering an interrogatory, Wyeth has failed to comply with the requirements of that rule. Wyeth has failed "to specify the records from which the answer may be derived or ascertained." Fed. R. Civ. P. 33(d). Wyeth has specified no documents, but, rather, has flatly refused to answer this interrogatory. Moreover, because this interrogatory seeks Wyeth's contentions, in addition to the identity of witnesses, it is impossible for Impax to derive the answer from documents. Wyeth's contentions are not stated in any documents. Accordingly, Wyeth cannot comply with the requirement of Rule 33(d) that "the burden of deriving or ascertaining the answer is substantially the same for the party serving the interrogatory as for the party served." *Id.* It is impossible for Impax to

divine Wyeth's contentions from documents, even if Wyeth had cited to documents in lieu of answering this interrogatory.

Fourth, Wyeth is not entitled to dictate what discovery vehicle Impax employs in getting the information it seeks. Impax is entitled to have Wyeth's sworn interrogatory responses containing this information. It is black letter law that "a party need not elect between interrogatories under Rule 33 and a request for admissions under Rule 36 but may proceed under both rules. *It may also employ both interrogatories under Rule 33 and a request for production under Rule 34.*" 8A Wright, Miller & Marcus, Federal Practice and Procedure: Civil 2d § 2169 at 267 (emphasis added). Moreover, "[a] claim of duplication is insufficient, unless all documentary material from which the interrogatory answers may be conveniently obtained has been previously provided." *Id.* § 2169 at 267 n.21 (citing *In re Folding Carton Antitrust Litigation*, 83 F.R.D. 260 (D.C. Ill. 1979).

REDACTED

Finally, Wyeth cannot avoid its obligation to answer this interrogatory by virtue of the fact that "Impax has subpoenaed documents bearing on this research project directly from Alza." (D.I. 89 at 7). Only Wyeth can identify Wyeth employees who were aware of the Alza formulations. The documents from Alza will not reveal this information. Moreover, Impax is entitled to have Wyeth's sworn contentions in response to these interrogatories and that information is most assuredly not in Alza's documents.

3. **Wyeth's argument that the Alza formulations do not invalidate the asserted patent claims highlights the need for Impax to discover that information.**

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Wyeth's arguments that the Alza prior art formulations do not invalidate the asserted claims highlights the need for Impax to take discovery on these formulations.

REDACTED

Impax is entitled to discover the full scope of this evidence and then form its own contentions and arguments as to how the Alza formulations are invalidating prior art. It is then for the Court to decide whether Wyeth or Impax is correct in its interpretation of this evidence. But Wyeth cannot avoid a trial on this question by refusing to produce the evidence altogether. This would be akin to an accused infringer stating that it need not provide discovery on the accused product based on the mere reassurance that it does not infringe. This is not the law. Impax contends that the prior art Alza formulations are invalidating prior art and Impax is therefore entitled to take discovery on those formulations notwithstanding the fact that Wyeth disagrees with Impax's contentions.

B. Discovery Regarding the Alza Formulations is Relevant to the Unenforceability of the Asserted Patent Claims, in Addition to the Invalidity of the Asserted Patent Claims.

Notwithstanding the fact that this interrogatory is relevant to invalidity on grounds of anticipation and obviousness, Wyeth further refuses to answer the interrogatory on the grounds that Impax has not yet pled a specific theory of unenforceability based on Wyeth's withholding of the Alza prior art from the PTO. Wyeth's argument disregards the broad and liberal scope of discovery under Rule 26.

In framing this argument, Wyeth focuses myopically on one phrase in Rule 26(b)(1), stating that "[p]arties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party." Fed. R. Civ. P. 26(b)(1). Wyeth ignores a further provision of that Rule stating that "[f]or good cause, the court may order discovery of any matter relevant to the subject matter involved in the action." *Id.*

This Court has interpreted “the subject matter of the action” broadly to mean that “discovery should ordinarily be allowed under the concept of relevancy unless it is clear that the information sought can have no possible bearing upon the subject matter of the action.” *In re Intel Corp. Microprocessor Antitrust Litigation*, 2007 WL 137152, *5 (D. Del. 2007). Due to the “subject matter” provision in Rule 26, “although one initially must look to the pleadings for the general boundaries of relevancy, the precise parameters of relevancy are fixed by the subject matter in issue and not the particular pleadings.” *United States v. Int’l Bus. Machs. Corp.*, 66 F.R.D. 180, 182 (S.D.N.Y. 1974); *see also Hickman v. Taylor*, 329 U.S. 495, 507 (1947) (“No longer can the time-honored cry of ‘fishing expedition’ serve to preclude a party from inquiring into the facts underlying his opponent’s case.”)

Here, notwithstanding Wyeth’s cry that Impax is embarked on a “fishing expedition,” (D.I. 89 at 13), Impax has established good cause to take this discovery on the subject matter of unenforceability. Impax has raised the subject matter of the unenforceability of the patents in its answer, (D.I. 32 ¶ 48). There is no dispute but that Impax pled with particularity that Wyeth committed inequitable conduct by its misrepresentation of clinical data to the PTO. (D.I. 32 ¶¶ 54-84). Now Impax has articulated a further basis for unenforceability linked to specific prior art formulations that Wyeth failed to disclose to the PTO. There is good cause for Impax to take discovery regarding these formulations to obtain the final details required to make out this claim with particularity because Impax has established how this information has a bearing on the subject matter of the unenforceability of the patents.

The cases Wyeth relies upon say nothing to the contrary. In *Solarex Corp. v. Arco Solar, Inc.*, 121 F.R.D. 163 (1988), the court refused to enforce a subpoena directing a third party publisher of an academic journal to disclose the identity of an independent reviewer who evaluated a prior art manuscript submitted for publication. *Id.* at 165-66 (cited in D.I. 89 at 13). The Court quashed the subpoena pursuant to Rule 26(c) after balancing the conflicting interests of the academic journal’s need for confidentiality against the relevance of the information to the accused infringer’s case. *Id.* at 170-79. It was in this context that the Court decided that the

information was not sufficiently relevant to an inequitable conduct claim to warrant overriding the competing interest of the third party academic journal's right to privacy. *Id.* at 177-78. The basis for this was that the accused infringer could only offer the barest speculation as to how the identity of the peer reviewer might be relevant to inequitable conduct. The accused infringer

urge[d] that the requested discovery may unearth evidence that 'the anonymous referee or some other person who had access to the manuscript [presumably via the referee] may have been associated with the inventor of the '521 patent,' and presumably, made the existence and contents of the manuscripts known to the inventor. Proof that the inventor knew of the manuscript and yet failed to disclose it to the patent examiner would thus assist Arco in establishing this defense to the infringement claims.

Id. at 177. The court quashed the subpoena because the accused infringer "conceded that any link between the anonymous referee and the inventor of the '521 patent is wholly speculative." *Id.* at 177.

Unlike in *Solarex*, here Impax is not merely speculating as to the connection between Wyeth and the prior art Alza formulations Wyeth withheld from the PTO.

REDACTED

Accordingly, the discovery Impax wishes to take is not a "fishing expedition," as Wyeth contends. The discovery is based in solid fact and evidence, and Impax wishes to take this discovery, not to trump up an unfounded claim of unenforceability, as in *Solarex*, but to obtain the final details in order to plead that claim with particularity. Moreover, unlike in *Solarex*, there is no consideration of third party interests or public policy to weigh against permitting this discovery. Impax wishes to take this discovery from its accuser, who has chosen to sue Impax for patent infringement in federal court and is now attempting to avoid an unenforceability challenge by blocking discovery of material prior art.

Nor is this case like *ResQNet.com, Inc. v. Lansa, Inc.*, 2004 WL 1627170 (S.D.N.Y. July 21, 2004) (cited in D.I. 89 at 14). That case involved a motion to quash the subpoena of the

patentee's prosecuting attorney where "No Defense of Inequitable Conduct Ha[d] Been Asserted." *Id.* at *3. Because the accused infringer had not pled inequitable conduct, there could be no claim that the subject matter of unenforceability had been raised for the purpose of determining the scope of discovery under Rule 26. Moreover, unlike in the present case, the Court had to weigh the fact that "depositions of opposing counsel are disfavored." *Id.* at *2 (citing *United States v. Yonkers Bd. of Educ.*, 946 F.2d 180, 185 (2d Cir. 1991)). Impax does not move to take the deposition of Wyeth's counsel here. Rather Impax is attempting to compel Wyeth to answer a simple, straightforward interrogatory.¹

Wyeth can cite to no case in which a court denied discovery on the subject matter of unenforceability where one theory of inequitable conduct had been adequately pled and where the accused infringer had cited to evidence in support of a further allegation of inequitable conduct, about which it sought to discover additional detail. The Court should not allow Wyeth to avoid facing this potentially case-dispositive defense by granting Wyeth's wish to avoid all discovery on the Alza formulations.

C. The Interrogatory is not "impossible to answer."

Wyeth's claim that the interrogatory is "impossible to answer" is specious. (D.I. 89 at 14-15). All of the information Impax seeks is uniquely within Wyeth's possession and for Wyeth to provide this information would impose little or not burden on Wyeth.

¹ The remaining cases on which Wyeth relies do not address the proper scope of discovery at all. Rather these are all cases on motions to strike pleadings of inequitable conduct based on arguments that the claims were inadequately pled. See *In re Pabst Licensing, GmbH Patent Litigation*, 174 F.Supp.2d 446, 448 (E.D. La. 2001); *Samsung Elecs. Co. v. Texas Instr. Inc.*, 1996 WL 343330, *3 (N.D. Tex. Apr. 18, 1996); *Chiron Corp. v. Abbott Labs.*, 156 F.R.D. 219, 221 (N.D. Cal. 1994). Accordingly, none of these cases involve the question as to whether there is good cause to take discovery on the subject matter of unenforceability where one theory of inequitable conduct had been adequately pled and where the accused infringer had cited to evidence in support of a further allegation of inequitable conduct, about which it sought to discover more detail.

First, only Wyeth knows which of its employees were involved in the Alza collaboration such that they can provide testimony on the Alza formulations. Wyeth's claim that it is unduly burdensome to identify all such persons is contradicted by the plain language of Rule 26, which provides that "[p]arties may obtain discovery regarding . . . the identity and location of persons having knowledge of any discoverable matter." Fed. R. Civ. P. 26(b)(1).

Second, the Court should reject Wyeth's claim that the interrogatory is overbroad because it asks Wyeth to identify persons with knowledge of the Alza formulations "even though the person may have had no connection with the prosecution of the patents." (D.I. 89 at 15). As Impax has explained, this interrogatory is relevant to invalidity, and not just to unenforceability. Accordingly, it is relevant which Wyeth witnesses have knowledge of the Alza formulations whether or not they were involved in patent prosecution.

Third, it is not unduly burdensome for Wyeth to provide its contentions as to why the prior art Alza formulations were not material to patentability and why Wyeth had no intent to deceive the PTO in withholding these formulations from the patent examiner. The Federal Rules provide a clear answer to Wyeth's complaints: "An interrogatory otherwise proper is not necessarily objectionable merely because an answer to the interrogatory involves an opinion or contention that relates to fact or the application of law to fact" Fed. R. Civ. P. 33(d). In adding this provision to the Federal Rules in 1970, the Advisory Committee stated that "[a]s to requests for opinions or contentions that call for the application of law to fact, they can be most useful in narrowing and sharpening the issues, which is a major purpose of discovery." Fed. R. Civ. P. 33, Advisory Committee Notes to Subdivision (b), 1970 Amendment. Rather than narrowing and sharpening the issues for trial by simply answering this interrogatory, Wyeth hopes to narrow the issues for trial by blocking all discovery regarding the Alza formulations altogether. The Court should reject this tactic and compel Wyeth to respond to Impax's Interrogatory No. 35.

III. CONCLUSION

For the foregoing reasons, the Court should grant Impax's motion to compel a response to Interrogatory No. 35.



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Dated: February 28, 2007

CERTIFICATE OF SERVICE

I hereby certify that on the 7th day of March, 2007, I electronically filed the foregoing document, **REDACTED VERSION OF DEFENDANT'S REPLY BRIEF IN SUPPORT OF MOTION TO COMPEL A RESPONSE TO INTERROGATORY NUMBER 35**, with the Clerk of the Court using CM/ECF which will send notification of such filing to the following:

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